A study on role of doctor of pharmacy in identification and reporting of adverse drug reactions in an antiretroviral therapy ward of a teritary care teaching hospital

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ABSTRACT

Clinical pharmacy is the branch of pharmacy in which pharmacists provide patient care that optimizes the use of medication and promotes health, wellness, and disease prevention. Clinical pharmacists care for patients in all health care settings but the clinical pharmacy movement initially began inside hospitals and clinics. Clinical pharmacists often work in collaboration with physicians, nurse practitioners and other healthcare professionals. The Clinical Pharmacist Stating explicitly that the clinical pharmacist cares for patients in all health care settings emphasizes two points: that clinical pharmacists provide care to their patients and that this practice can occur in any practice setting. The clinical pharmacist's application of evidence and evolving sciences points out that clinical pharmacy is a scientifically rooted discipline the application of legal, ethical, social, cultural, and economic principles serves to remind us that clinical pharmacy practice also takes into account societal factors that extend beyond science.

Keywords: doctor of pharmacy, antiretroviral therapy, teritary care teaching hospital

INTRODUCTION

Clinical pharmacy is the branch of pharmacy in which pharmacists provide patient care that optimizes the use of medication and promotes health, wellness, and disease prevention. Clinical pharmacists care for patients in all health care settings but the clinical pharmacy movement initially began inside hospitals and clinics. Clinical pharmacists often work in collaboration with physicians, nurse practitioners and other healthcare professionals. The Clinical Pharmacist stating explicitly that the clinical pharmacist cares for patients in all health care settings emphasizes two points: that clinical pharmacist provides care to their patients and that this practice can occur in any practice setting. The clinical pharmacist's application of evidence and evolving sciences points out that clinical pharmacy is a scientifically rooted discipline the application of legal, ethical, social, cultural, and economic principles serves to remind us that clinical pharmacy practice also takes into account societal factors that extend beyond science.

Adverse Drug Reaction

However according to World Healthcare Organization (WHO) adverse drug reaction (ADR) can be defined as "any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function."

Adverse Drug Events

The drugs being intensive in physiological / pharmacological actions are capable of causing an injury in some suitable patients in the usual course of treatment and may not happen on all patients like ADRs. Adverse drug events are injuries resulting from the medical management. It can occur in any health care setting, including: inpatient, outpatient and long-term care settings.

Side Effects

Side effects are due to pharmacological interactions with living system in general. The drugs are usually

administered to the whole of the body making pharmacological reactions to happen.

Pharmacovigilance

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. WHO established its Programme for International Drug Monitoring in response to the thalidomide disaster detected in 1961.

Aims of Pharmacovigilance Program

The aim of the pharmacovigilance is to gather evidence and establish the sever ADR resulting from using of drugs for example the drug Nimesulide was approved by regulatory agencies as safe medication for use in management of RA and Analgesics.

Classification of Adverse Drug Reactions

According to Rawlins ADRs can be classified into Type A and Type B. Type A ADRs are dose dependent and predictable from the known pharmacology of the drug. Whereas Type B reactions are not dose dependent and unpredictable. The classification has gradually been extended to Type A-F. Type A: Augmented pharmacologic effects, Type B: Bizarre effects (or idiosyncratic), Type C: Chemical effects, Type D: Delayed effects, Type E: End-of-treatment effects, and Type F: Failure of therapy.

Adverse Drug Reactions Are Needed To Be Monitored

The ADRs effect may have a consequence extending to future human generation by changing the genetic properties. The ADRs are of no use for therapeutic purpose. However the ADR monitoring can give an insight into other possible applications and drug development leading to new drug discovery. The off-label use of medicines can be a useful hint for extending the drug use after getting the approval for the off-label use by regulatory authorities.

Who Can Report The Adverse Drug Reactions

As per the pharmacovigilance program all Health professionals working in the field of delivering the health care (both conventional and unconventional) like physicians, dentists, nurses, pharmacists, can report suspected adverse drug reactions by letter, phone, fax, e-mail, or by personal contact to any of the five adverse drug reaction monitoring centers located across the country.

Whom to Report the Adverse Drug Reactions

The ADRs are of public interest and there is a system of collection, documenting and reporting. The matters of ADRs are of detrimental for a pharmaceutical industry prospect of marketing. Hence an independent public funded national and international pharmacovigilance centers are established. These centers receive the reports of ADRs in format designed by the pharmacovigilance Program. A method for assigning the probability of a reported or suspected ADR (e.g., confirmed or definite, likely, possible, and unlikely) should be developed to categorize each ADR subjective questions and the professional judgment of a Pharmacist[46] can be used as additional tools to determine the probability of an ADR.

Questions might include the following:

a. Was there a temporal relationship between the onset of drug therapy and the adverse reaction?
b. Was there a dechallenge; i.e., did the signs and symptoms of the adverse reaction subside when the drug was withdrawn?
c. Can signs and symptoms of the adverse reaction be explained by the patient's disease state?
d. Were there any laboratory tests that provide evidence for the reaction being an ADR?
e. What was the patient's previous general experience with the drug?
f. Did symptoms return when the agent was readministered?
g. method for ranking ADRs by severity should be established.
h. Description of each suspected ADR and the outcomes from the event should be documented in the patient's medical record.
i. Serious or unexpected ADRs should be reported to the Food and Drug Administration (FDA) or the drug's manufacturer (or both)
j. All ADR reports should be reviewed and evaluated by a designated multidisciplinary committee (e.g., a pharmacy and therapeutics committee).

Scales to Assess the Adverse Drug Reactions

The adverse drug reaction scales are to establish a causal relationship between the drug and the adverse event. The Naranjo ADR probability scale, WHO- Uppsala Monitoring Centre causality categories and Severity of reported ADRs by Modified Hartwig and Siegel scale are used to assess the ADRs.

Scales used to report adverse drug reactions:

The causality assessment system proposed by the World Health Organization Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre (WHO–UMC), and the Naranjo Probability Scale are the generally accepted and most widely used methods for causality assessment in clinical practice as they offer a simple methodology. The above scales are structured, transparent, consistent, and easy to apply assessment methods.

"Naranjo ADR Probability Scale".

The Naranjo adverse drug reaction (ADR) probability scale. The Naranjo criteria classify the probability that an adverse event is related to drug therapy based on a list of weighted questions, which examine factors such as the temporal association of drug administration and event occurrence, alternative causes for the event, drug levels, dose – response relationships and previous patient experience with the medication.

The ADR is assigned to a probability category from the total score as follows:

Definite if the overall score is 9 or greater, probable for a score of 5-8, possible for 1-4 and doubtful if the score is 0.

Table1.1: Naranjo ADR Probability Scale

The Naranjo adverse drug reaction probability scale; To assess the adverse drug reaction, please answer the following questionnaire and give the pertinent score	**Yes**	**No**	**Do not know**	**Score**
1. Are there previous *conclusive* reports on this reaction?	+1	0	0	
2. Did the adverse event occur after the suspected drug was administered?	+2	-1	0	
3. Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?	+1	0	0	
4. Did the adverse reaction reappear when the drug was readministered?	+2	-1	0	
5. Are there alternative causes (other than the drug) that could have on their own caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the blood detected in the blood (or other fluids) in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in *any* previous exposure?	+1	0	0	

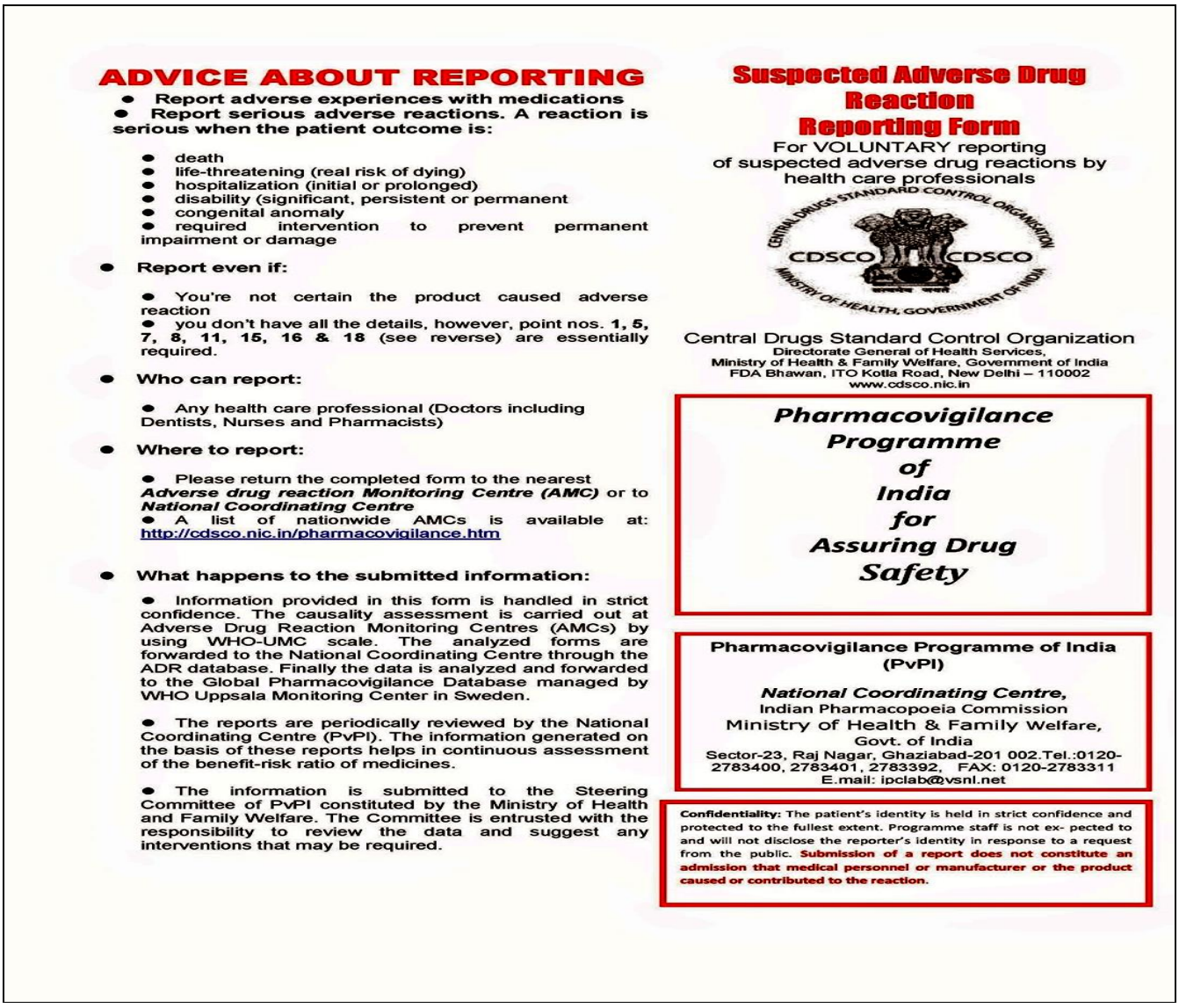
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	
			Total	

Table 1.2 WHO–UMC causality categories

Causality term	Assessment criteria (all points should be reasonably complied)
Certain	Event or laboratory test abnormality, with plausible time relationship to drug intake Cannot be explained by disease or other drugs Response to withdrawal plausible (pharmacologically, pathologically) Event definitive pharmacologically or phenomenologically (ie, an objective and specific medical disorder or a recognized pharmacologic phenomenon) Rechallenge satisfactory, if necessary
Probable/likely	Event or laboratory test abnormality, with reasonable time relationship to drug intake Unlikely to be attributed to disease or other drugs Response to withdrawal clinically reasonable Rechallenge not required
Possible	Event or laboratory test abnormality, with reasonable time relationship to drug intake Could also be explained by disease or other drugs Information on drug withdrawal may be lacking or unclear
Unlikely	Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) Disease or other drugs provide plausible explanation
Conditional/unclassified	Event or laboratory test abnormality More data for proper assessment needed, or Additional data under examination
Unassessable/unclassifiable	Report suggesting an adverse reaction Cannot be judged because information is insufficient or contradictory Data cannot be supplemented or verified

Role of Pharmacist in Adverse Drug Reaction Monitoring

The pharmacist being in the field of clinical, community and hospital settings is likely to get to know about an ADR event the pharmacist are also considered as expert Professionals who are consulted for drug information about an ADR management. The Pharmacist are to participate in ADR reporting as a professional obligation and responsibility in the capacity of stakeholders for patient safety.



ADVICE ABOUT REPORTING

- Report adverse experiences with medications
- Report serious adverse reactions. A reaction is serious when the patient outcome is:
  - death
  - life-threatening (real risk of dying)
  - hospitalization (initial or prolonged)
  - disability (significant, persistent or permanent
  - congenital anomaly
  - required intervention to prevent permanent impairment or damage
- Report even if:
  - You're not certain the product caused adverse reaction
  - you don't have all the details, however, point nos. **1, 5, 7, 8, 11, 15, 16 & 18** (see reverse) are essentially required.
- Who can report:
  - Any health care professional (Doctors including Dentists, Nurses and Pharmacists)
- Where to report:
  - Please return the completed form to the nearest ***Adverse drug reaction Monitoring Centre (AMC)*** or to ***National Coordinating Centre***
  - A list of nationwide AMCs is available at: http://cdsco.nic.in/pharmacovigilance.htm
- What happens to the submitted information:
  - Information provided in this form is handled in strict confidence. The causality assessment is carried out at Adverse Drug Reaction Monitoring Centres (AMCs) by using WHO-UMC scale. The analyzed forms are forwarded to the National Coordinating Centre through the ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center in Sweden.
  - The reports are periodically reviewed by the National Coordinating Centre (PvPI). The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
  - The information is submitted to the Steering Committee of PvPI constituted by the Ministry of Health and Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

Suspected Adverse Drug Reaction Reporting Form

For VOLUNTARY reporting of suspected adverse drug reactions by health care professionals

CDSCO CDSCO

Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India
FDA Bhawan, ITO Kotla Road, New Delhi – 110002
www.cdsco.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

Pharmacovigilance Programme of India (PvPI)

National Coordinating Centre,
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare,
Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201 002.Tel.:0120-2783400, 2783401, 2783392, FAX: 0120-2783311
E.mail: ipclab@vsnl.net

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not ex- pected to and will not disclose the reporter's identity in response to a request from the public. **Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.**

Figure1.1: suspected adverse drug reaction reporting form

Role of Uppsala Monitoring Centre in Adverse Drug Reactions Monitoring

The Uppsala Monitoring Centre is the global Pharmacovigilance center promoted by WHO. The Uppsala Monitoring Centre is the final destination for ADR reports which arrives from different countries and is reviewed for signals of ADRs. Uppsala Centre also conducts training programs and helps the establishment of country, regional and local ADR reporting centers. They also train human resources in the area of software applications for ADR monitoring.

Benefits of Adverse Drug Reactions Monitoring

The ADR monitoring is a gate way to identify the risks due to use of drugs and also an opportunity to re-evaluate the risk-benefit analysis serving as updated guidelines for prescription writing. If ADR is sever than there can be a revival of licensing for the drug this becomes as a continuous engagement for the industry who is involved in sale of the drugs. There is a regulatory reform even in India to run, collect and submit periodical reports of Pharmacovigilance on selected products in order to continue with licensing of further sale of drug.

The Terminologies Used To Code the Adverse Drug Reactions

MedDRA is fully implemented in the WHO global safety database allowing entry and retrieval of information in either MedDRA or WHO- Adverse Reactions Terminology is used to code the ADRs. The

structure of MedDRA is System organ class (SOC),High level group term (HLGT), High level term (HLT), Preferred term (PT) and Lowest level term (LLT).SOC is the highest level of the terminology, and distinguished by anatomical or physiological system, etiology, or purpose. HLGT is subordinate to SOC, Super ordinate descriptor for one or more HLTs. HLT is subordinate to HLGT, Super ordinate descriptor for one or more PTs.PT is represents a single medical concept.[66]

Seriousness And Severity

The American Food and Drug Administration defines a serious adverse event as one when the patient outcome is one of the following:[6]

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability - significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life.
- Congenital anomaly
- Requires intervention to prevent permanent impairment or damage
- As research better explains the biochemistry of drug use, fewer ADRs are Type B and more are Type A.

Common mechanisms are:

Abnormal pharmacokinetics due to

- Genetic factors
- Comorbid disease states
- Synergistic effects between either a drug and a diseasetwo drugs

ABNORMAL PHARMACOKINETICS

Comorbid disease states

Various diseases, especially those that cause renal or hepatic insufficiency, may alter drug metabolism. Resources are available that report changes in a drug's metabolism due to disease states.

Genetic factors

Abnormal drug metabolism may be due to inherited factors of either Phase I oxidation or Phase II conjugation. Pharmacogenomics is the study of the inherited basis for abnormal drug reactions.

Assessing causality

Causality assessment is used to determine the likelihood that a drug caused a suspected ADR. There are a number of different methods used to judge causation, including the Naranjo algorithm, the Venulet algorithm and the WHO causality term assessment criteria. Each have pros and cons associated with their use and most require some level of expert judgement to apply.

Monitoring bodies

On an international level, the WHO runs the Uppsala Monitoring Centre, and the European Union runs the European Medicines Agency (EMEA).

In the United States, the Food and Drug Administration (FDA) is responsible for monitoring post-marketing studies. In Canada, the Marketed Health Products Directorate of Health Canada is responsible for the surveillance of marketed health products.

In Australia, the Therapeutic Goods Administration (TGA) conducts postmarket monitoring of therapeutic products.

PRESENT RESEARCH STUDY

AIM: The study aims to assess the role of clinical pharmacist in identification and reporting of adverse drug reactions in antiretroviral therapy wards of a teritary care teaching hospital.

OBJECTIVES: The Main Objective Of The Present Study Includes Preventing the medication related problems (ADVERSE DRUG REACTIONS),Monitoring of ADVERSE DRUG REACTIONS , Identifying and minimizing medication related problems, Improving Patient safety initiatives, Providing better therapy to the large number of patients, Improving the Patient health related outcomes.

METHODOLOGY:

Study Design: It is a Prospective observational study.

Study Period: The Present study was conducted for a period of 8 months from july 2016 to feburary 2017.

Study site : The Present study was conducted in ART Department at Rajiv Gandhi Institute of Medical Sciences (RIMS), Kadapa.

Sample size: The Patients admitted in hospital during the study period of 8 months it was 100Patients.

Source of Data: All the patients satisfying the inclusion criteria were selected from ART department in Rajiv Gandhi institute of medical sciences (RIMS) Government Hospital, Kadapa. All the required data was collected from patients through Patient representative interview and case sheets and treatment charts.

Inclusion criteria

Patients with aging above 18 years.

Patients having previous history of medical, medication problems in ART.

The Patients who are willing to participate in the study.

Exclusion criteria

Patients who are not willing to Participate in the study.

RESULTS

AGE WISE DISTRIBUTION OF MALE POPULATION:

In this study total of 100 patients were enrolled in the study. The males population is 55.The age wise male Patients population ranges from 2(3.6363) Patients were in the age group of 10-20 years , 27(49.09)Patients were in the age group of 20-30 years, 12(21.81) patients were in the age group of 30-40 years ,9(16.3636) patients were in the age group of 40-50 years ,5 (9.0909)Patients were in the age group of 50-60 years.

Table 1.1 Age wise distribution of male patients

Age in years	Total number of Patients	Percentage (%)
10-20	2	3.6363
20-30	27	49.09
30-40	12	21.81
40-50	9	16.3636
50-60	5	9.0909
Total	**55**	**55**
		P value <0.0001

Fig 1.1 Age wise distribution of male patients

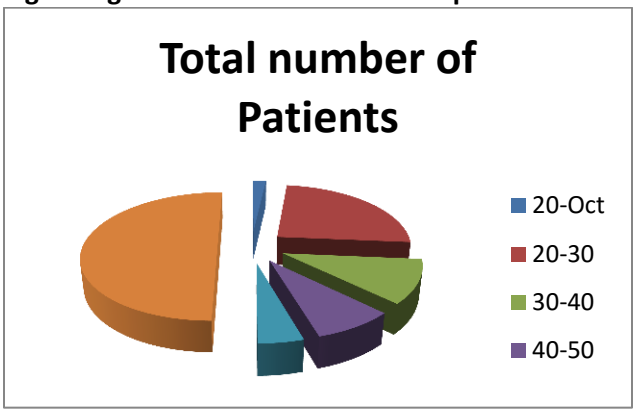
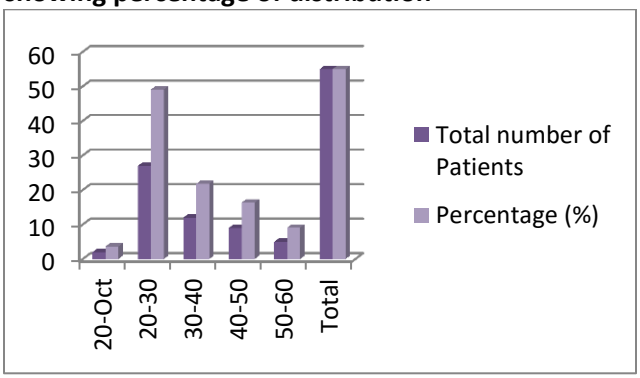


Fig 1.2 Age wise distribution of male patients showing percentage of distribution



AGE WISE DISTRIBUTION OF FEMALE POPULATION

In this study total of 100 patients were enrolled in the study. The Females population is 45.The age wise Female patients population ranges from the 0 Patients were in the age group of 10-20 and 16 (35.5) were from 20-30 years, 19(42.22) Patients were in the age group of 30-40 years and 5 (11.111)patients were in the age group of 40-50 years and 3(6.66)patients were in the age group of 50-60 years, 2(4.44) patients were in the age group of 60-70 years, 0 patients were in the age group of 70-80 years.

Table 1.2 Age wise distribution of Female Patients

Age	Total	Percentage (%)
10-20	0	0
20-30	16	35.5
30-40	19	42.22
40-50	5	11.111
50-60	3	6.66666
60-70	2	4.444
70-80	0	0
Total	**45**	**45**
		P value <0.0001

Fig 1.3 Age wise distribution of Female patients.

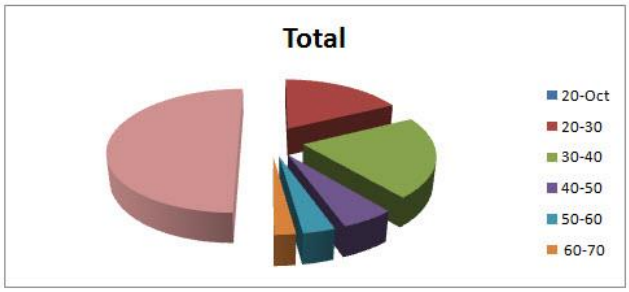


Fig 1.4 Age wise distribution of Female patients showing percentage of distribution.

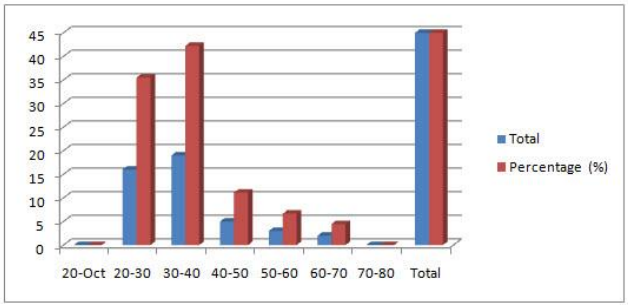


Table 1.3 Showing Medical Diagnosis Cases of HIV with other Comorbidities.

VARIOUS MEDICAL DIAGNOSIS CASES	TOTAL
HIV WITH HYPERTENSION AND DIABETES MELLITUS	15
HIV WITH PNEUMONIA AND URINARY TRACT INFECTION	11
HIV WITH TUBERCULOSIS	16
HIV WITH TUBERCULOSIS AND LEPROSY	11
HIV WITH SEPTICEMIA	7
HIV WITH HYPERTENSION	9
HIV WITH GROSS ANEMIA	10
HIV WITH AGRANULOCYTOSIS	13
HIV WITH ASTHMA AND COPD	3
HIV WITH OTHER COMORBIDITIES	5
Total Cases	**100**

Table 1.4: TYPES AND NUMBER OF ADVERSE DRUG REACTIONS

Type of ADR	Number ADRS	Percentage (%)
TYPE-A	56	51.851851
TYPE-B	46	42.59259
TYPE-C	6	5.55
Total	**108**	**100**

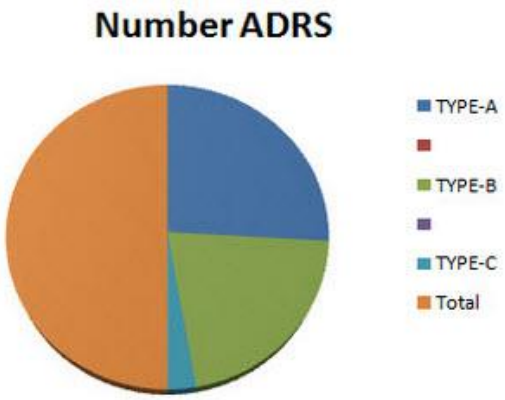


Figure 1.5 : Types Of ADRS And Their Distribution

DISCUSSION

In this study total of 100 patients were enrolled in the study. The males population is 55.The age wise male Patients population ranges from 2(3.6363) Patients were in the age group of 10-20 years , 27(49.09)Patients were in the age group of 20-30 years, 12(21.81) patients were in the age group of 30-40 years ,9(16.3636) patients were in the age group of 40-50 years ,5 (9.0909)Patients were in the age group of 50-60 years. The Females population is 45.The age wise Female patients population ranges from the 0 Patients were in the age group of 10-20 and 16 (35.5) were from 20-30 years, 19(42.22) Patients were in the age group of 30-40 years and 5 (11.111)patients were in the age group of 40-50 years and 3(6.66)patients were in the age group of 50-60 years ,2(4.44) patients were in the age group of 60-70 years ,0 patients were in the age group of 70-80 years. A total 108 ADRS were screened during the study period. In which TYPE-A ADRS are 56(51.851851) , TYPE-B ADRS are 46 (42.59259) and TYPE-C ADRS are 6(5.55).

CONCLUSION

The present study concludes that clinical pharmacist play a key role in patient safety, Particularly in ART department they are important for educating guiding the health care professionals related to safety use of medications. Even through drug related problems were founded but after reporting information to physicians we are minimizing harmful to Patient's. In future clinical pharmacy services is one of the effective services in hospital to improve the quality of life of patient's in the hospital. Implementing such a practices in the hospitals and country we can make the country and society becomes free of diseases.

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